



Soleno Therapeutics Announces Presentation of DCCR Data at the 11th International Prader-Willi Syndrome Organisation Conference

July 11, 2022

REDWOOD CITY, Calif., July 11, 2022 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced presentations at the 11th International Prader-Willi Syndrome Organisation (IPWSO) Conference, held on July 6-10, 2022, in Limerick, Ireland.

Presentation details:

11th International Prader-Willi Syndrome Organisation Conference

Title: *Long-Term Safety of Diazoxide Choline Extended-Release (DCCR) Tablets in Patients with Prader-Willi Syndrome*

Format: Oral Presentation

Presenter: Jennifer L. Miller, M.D., University of Florida School of Medicine

Title: *Application of a Novel Hybrid Natural Language Processing-Qualitative Analytic Method to Characterize Efficacy of DCCR in Prader-Willi Syndrome*

Format: Oral Presentation

Presenter: Adam Pittman, Folia Health

Title: *Preliminary Findings from the Final Qualitative Interview with Caregiver Participants in a PWS Outcomes Assessment of DCCR*

Format: Poster Presentation

Presenter: Siri Bolding, Casimir

Title: *Comparing Hyperphagia and Problem Behaviors in Participants with Prader-Willi syndrome (PWS) Receiving Diazoxide Choline Extended-Release (DCCR) with Matched Participants in PATH for PWS (PfPWS)*

Format: Poster Presentation

Presenter: Theresa Strong, Ph.D., Foundation for Prader-Willi Research

The presentations by Mr. Pittman and Ms. Bolding included the results from the analysis of caregiver interviews conducted after at least 12 months of investigational, open-label DCCR treatment. The interviews were available for 51 patients who were enrolled in the DCCR Phase 3 program. Casimir Inc (Casimir) completed semi-structured interviews with these participants and interview transcripts were manually coded by trained coders who subsequently analyzed the coded interviews in accordance with a pre-specified statistical analysis plan. Folia Health used the Casimir-prepared transcripts and conducted a semi-automated analysis using Natural Language Processing (NLP) methods.

In the Casimir analysis, 33 (65%), 30 (59%), and 31 (61%) caregivers described a positive change in food-related behavior, non-food-related behavior, and daily life, respectively. Of these, 26 (51%), 20 (39%), and 25 (49%), respectively, reported a positive change with major impact. The analysis was based on thematic coding of 12-month interview data by trained, blinded researchers.

The Folia Health NLP analysis of interview transcripts identified seven problematic behavior domains. 88% of participants experienced positive change in at least one behavior with DCCR treatment. Positive change was detected across all seven identified domains, most commonly in food seeking (72%) and daily life (73%).

"Both analyses of caregiver interviews presented at IPWSO summarize the positive changes across all seven identified behavioral domains, in both food- and non-food-related behaviors, as well as daily life, while receiving long-term DCCR. These findings, combined with the totality of data generated in our DCCR program, continue to support the potential DCCR has to be a safe and tolerable therapy that may provide meaningful benefit to people with PWS, caregivers, and families," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics.

The presentations by Dr. Miller and Dr. Strong consisted largely of data presented at prior meetings.

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births in the U.S. The hallmark symptom of this disorder is hyperphagia, a chronic feeling of insatiable hunger that severely diminishes the quality of life for PWS patients and their families. Additional characteristics of PWS include behavioral problems, cognitive disabilities, low muscle tone, short stature (when not treated with growth hormone), the accumulation of excess body fat, developmental delays, and incomplete sexual development. Hyperphagia can lead to significant morbidities (e.g., obesity, diabetes, cardiovascular disease) and mortality (e.g., stomach rupture, choking, accidental death due to food seeking behavior). In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia and 92.9 % body composition as the most important or a very important symptom to be relieved by a new medicine. There are currently no approved therapies to treat the hyperphagia/appetite, metabolic, cognitive function, or behavioral aspects of the disorder. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the U.S. and E.U., and Fast Track Designation in the U.S.

About DCCR (Diazoxide Choline) Extended-Release Tablets

DCCR is a novel, proprietary extended-release dosage form containing the crystalline salt of diazoxide and is administered once-daily. The parent molecule, diazoxide, has been used for decades in thousands of patients in a few rare diseases in neonates, infants, children and adults, but has not been approved for use in PWS. Soleno conceived of and established extensive patent protection on the therapeutic use of diazoxide and DCCR in patients with PWS. The DCCR development program is supported by data from five completed Phase 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in PWS patients. In the PWS Phase 3 study, DCCR showed promise in addressing hyperphagia, the hallmark symptom of PWS, as well as several other symptoms such as aggressive/destructive behaviors, fat mass and other metabolic parameters.

About Soleno Therapeutics, Inc.

Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company's lead candidate, DCCR extended-release tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase 3 clinical development program. For more information, please visit www.soleno.life.

About Folia Health

Folia is a patient-driven Health-IOs (Individual Operating System) that enables individuals to easily take an active role in their care, while contributing to precision diagnostics, patient-centered drug development, & better care for complex diseases. Folia's rich longitudinal data and proprietary analytic methods provide a vital and missing piece in the emergence of a home-centered, data-driven healthcare ecosystem. Discover how to harness the power of patient and caregiver knowledge at www.foliahealth.com.

About Casimir

Casimir is a Contract Research Organization (CRO) that develops novel outcomes for decentralized and hybrid trials in order to better understand disease progression and treatment benefit. Casimir was recently acquired by Emmes, a global full-service CRO dedicated to excellence in supporting the advancement of public health and biopharmaceutical innovation. To learn more about how our research is making a positive impact on human health, visit www.emmes.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of PWS. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including the risks and uncertainties associated with market conditions, as well as risks and uncertainties inherent in Soleno's business, including those described in the company's prior press releases and in the periodic reports it files with the SEC. The events and circumstances reflected in the company's forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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Source: Soleno Therapeutics